

WHAT IS CLAIMED IS:

1. A method of treatment of a blood vessel, comprising:
 - advancing an evacuation sheath assembly into the blood vessel;
 - prior to advancing a device across a stenosis to be treated, stopping normal antegrade blood flow in the blood vessel proximate to the stenosis;
 - treating the stenosis while blood flow is stopped; and
 - inducing retrograde blood flow within the blood vessel to carry embolic material dislodged during treating into the evacuation sheath assembly.
2. The method of claim 1, wherein advancing the evacuation sheath assembly includes advancing the evacuation sheath assembly from a distal end of a guide catheter.
3. The method of claim 1, wherein stopping blood flow includes creating a first seal between a distal portion of the evacuation sheath assembly and the blood vessel.
4. The method of claim 3, wherein creating a first seal includes inflating a distal sealing balloon.
5. The method of claim 3, wherein creating a first seal includes expanding an evacuation lumen of the evacuation sheath assembly within the blood vessel.
6. The method of claim 5, wherein expanding includes inflating a plurality of balloons surrounding the evacuation lumen.
7. The method of claim 5, wherein expanding includes pulling an actuation wire attached to a distal end of the evacuation lumen.

8. The method of claim 5, wherein expanding includes moving a delivery sheath holding the evacuation lumen in a compressed state.

9. The method of claim 3, wherein stopping blood flow further comprises creating a second seal between a guide catheter and a proximal portion of the evacuation sheath assembly.

10. The method of claim 9, wherein creating a second seal includes inflating a proximal sealing balloon.

11. The method of claim 1, wherein inducing retrograde blood flow includes applying a vacuum through the evacuation sheath assembly.

12. The method of claim 1, wherein treating the stenosis includes advancing an angioplasty catheter to the stenosis.

13. The method of claim 1, wherein treating the stenosis includes advancing a stent delivery system to the stenosis.

14. The method of claim 1, further comprising injecting contrast material into the blood vessel after stopping blood flow.

15. The method of claim 1, further comprising measuring pressure in the blood vessel prior to stopping blood flow.

16. The method of claim 1, further comprising measuring pressure in the blood vessel subsequent to stopping blood flow.

17. The method of claim 1, further comprising:
measuring a first pressure in the blood vessel prior to stopping flow;
measuring a second pressure in the blood vessel subsequent to stopping flow; and

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comparing the first and second pressures to confirm that blood flow has been stopped.

18. The method of claim 1, further comprising advancing a guidewire across the stenosis subsequent to stopping blood flow.

19. The method of claim 18, further comprising inducing retrograde blood flow within the blood vessel to remove embolic material dislodged by advancement of the guidewire.

20. The method of claim 1, wherein inducing retrograde flow includes venting pressure in a collection device in fluid communication with the blood vessel with normal antegrade blood flow stopped.

21. The method of claim 19, wherein inducing retrograde flow includes venting pressure in a collection device in fluid communication with the blood vessel with normal antegrade blood flow stopped.

22. The method of claim 21, wherein inducing retrograde flow further includes applying suction to the collection device.

23. The method of claim 19, further comprising stopping retrograde flow after embolic material dislodged by advancement of the guidewire is removed from the blood vessel.

24. The method of claim 23, further comprising injecting contrast material into the blood vessel after the retrograde flow is stopped.

25. The method of claim 15, wherein measuring the pressure in the blood vessel includes placing a pressure transducer in fluid communication with the blood vessel.

26. The method of claim 25, wherein the pressure transducer is in fluid communication with a lumen of a guide catheter.

27. The method of claim 25, wherein the pressure transducer is in fluid communication with a lumen of the evacuation sheath assembly.

28. The method of claim 1, wherein the blood vessel is a coronary artery.

29. The method of claim 1, wherein the blood vessel is a saphenous vein graft.

30. A method for treating a diseased blood vessel, comprising:
positioning a guide catheter proximate to the diseased blood vessel;
positioning an evacuation sheath assembly within the diseased blood vessel;
prior to advancing a device across a diseased area of the blood vessel, stopping normal antegrade blood flow in the blood vessel proximate to the diseased area;
advancing a guidewire through the guide catheter and the evacuation sheath assembly across the diseased area of the blood vessel while the blood flow is stopped;
causing retrograde flow of blood within the diseased blood vessel to remove embolic debris dislodged by advancement of the guidewire;
advancing an interventional catheter into the blood vessel to treat the diseased area of the blood vessel; and
causing retrograde flow of blood within the vessel to remove embolic debris dislodged by advancement of the interventional catheter.

31. The method of claim 30, wherein causing retrograde flow of blood within the diseased blood vessel includes occluding normal antegrade blood flow within the diseased blood vessel.

32. The method of claim 31, wherein causing retrograde flow of blood further includes venting a collection device in fluid communication with the diseased blood vessel.

33. The method of claim 31, wherein causing retrograde flow of blood further includes applying suction to the blood vessel.

34. The method of claim 30, further comprising injecting a contrast dye into the blood vessel while blood flow is stopped prior to advancing the guidewire.

35. The method of claim 30, further comprising injecting a contrast dye into the blood vessel while blood flow is stopped prior to advancing the interventional catheter.

36. The method of claim 30, further comprising measuring pressure in the diseased blood vessel prior to stopping normal antegrade blood flow.

37. The method of claim 36, further comprising creating a seal within the diseased blood vessel subsequent to measuring the pressure in the blood vessel.

38. The method of claim 37, further comprising measuring pressure in the diseased blood vessel subsequent to creating the seal within the diseased blood vessel.

39. The method of claim 30, wherein the diseased blood vessel is a coronary artery.

40. The method of claim 30, wherein the diseased blood vessel is a saphenous vein graft.

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41. A method of performing a procedure on a blood vessel, comprising:
 - positioning a guide catheter proximate to the blood vessel;
 - positioning an evacuation sheath assembly within the guide catheter;
 - measuring pressure in the blood vessel to obtain a first pressure measurement;
 - creating a seal between the evacuation sheath assembly and the blood vessel;
 - measuring pressure in the blood vessel to obtain a second pressure measurement; and
 - comparing the first and second pressure measurements.
42. The method of claim 41, wherein measuring pressure in the blood vessel to obtain the first and second pressure measurements includes placing a pressure transducer in fluid communication with the blood vessel.
43. The method of claim 42, wherein the pressure transducer is in fluid communication with a lumen of the guide catheter.
44. The method of claim 42, wherein the pressure transducer is in fluid communication with a lumen of the evacuation sheath assembly.
45. The method of claim 41, further comprising forming a second seal between the evacuation sheath assembly and the guide catheter prior to obtaining the second pressure measurement.
46. The method of claim 41, further comprising releasing the seal and forming a new seal if the first pressure measurement is substantially the same as the second pressure measurement.

47. The method of claim 41, further comprising commencing an interventional operation within the blood vessel if the first pressure is substantially greater than the second pressure.

48. The method of claim 41, further comprising inducing retrograde blood flow in the blood vessel.

49. The method of claim 48, wherein inducing retrograde blood flow includes venting a collection device in fluid communication with the blood vessel.

50. The method of claim 49, wherein inducing retrograde blood flow further includes applying suction to the collection device.

51. The method of claim 41, wherein creating the seal includes expanding a sealing surface of the evacuation sheath assembly.

52. The method of claim 51, wherein creating the seal includes expanding an evacuation lumen of the evacuation sheath assembly.

53. The method of claim 52, wherein expanding includes inflating a plurality of balloons surrounding the evacuation lumen.

54. The method of claim 52, wherein expanding includes pulling an actuation wire attached to a distal end of the evacuation lumen.

55. The method of claim 52, wherein expanding includes moving a delivery sheath holding the evacuation lumen in a compressed state.

56. The method of claim 51, wherein the sealing surface is on a distal portion of the evacuation sheath assembly.

57. The method of claim 56, wherein the sealing surface is an inflatable balloon.

58. The method of claim 45, wherein forming the second seal includes expanding a sealing surface of the evacuation sheath assembly.

59. The method of claim 58, wherein the sealing surface is on a proximal portion of the evacuation sheath assembly.

60. The method of claim 59, wherein the sealing surface is an inflatable balloon.

61. The method of claim 45, wherein creating the seal includes expanding a first sealing surface of the evacuation sheath assembly and wherein forming the second seal includes expanding a second sealing surface of the evacuation sheath assembly.

62. The method of claim 61, wherein the first sealing surface is on a distal portion of the evacuation sheath assembly and the second sealing surface is on a proximal portion of the evacuation sheath assembly.

63. The method of claim 62, wherein the first and second sealing surfaces are inflatable balloons.

64. The method of claim 41, wherein the blood vessel is a coronary artery.

65. The method of claim 41, wherein the blood vessel is a saphenous vein graft.

66. A method of isolating fluid communication between a catheter and a blood vessel to facilitate visualization of the blood vessel, comprising:
advancing a catheter proximate to the blood vessel;
advancing an evacuation sheath assembly including a sealing surface through the catheter and partially into the blood vessel;

expanding the sealing surface to create a seal between the blood vessel and the evacuation sheath assembly thereby stopping normal blood flow in the vessel; and

injecting contrast dye into the blood vessel while the normal blood flow is stopped.

67. The method of claim 66, further comprising expanding a second sealing surface of the evacuation sheath assembly to create a second seal between the catheter and the evacuation sheath assembly.

68. The method of claim 66, wherein the catheter is a guide catheter.

69. The method of claim 66, wherein expanding the sealing surface includes expanding an evacuation lumen of the evacuation sheath assembly.

70. The method of claim 69, wherein expanding includes inflating a plurality of balloons surrounding the evacuation lumen.

71. The method of claim 69, wherein expanding includes pulling an actuation wire attached to a distal end of the evacuation lumen.

72. The method of claim 69, wherein expanding includes moving a sheath holding the evacuation lumen in a compressed state.

73. The method of claim 66, wherein expanding the sealing surface includes expanding a sealing surface on a distal portion of the evacuation sheath assembly.

74. The method of claim 69, wherein expanding the sealing surface includes inflating a balloon.

75. An evacuation sheath assembly, comprising:

a tube having first and second lumens and first and second sealing surfaces, wherein the first lumen is an evacuation lumen configured to be placed in fluid communication with a bloodstream and wherein the second lumen is an inflation lumen in fluid communication with at least one of the first and second sealing surfaces; and
a shaft in fluid communication with the inflation lumen and configured to connect to an inflation source.

76. The assembly of claim 75, wherein the first and second sealing surfaces are balloons.

77. The assembly of claim 75, wherein the first and second sealing surfaces are elastomeric.

78. The assembly of claim 75, wherein the first sealing surface is located on a proximal portion of the tube and the second sealing surface is located on a distal portion of the tube.

79. The assembly of claim 78, wherein the second sealing surface is expandable to a greater diameter than the first sealing surface.

80. The assembly of claim 75, wherein the evacuation lumen is configured to expand from a delivery configuration to an evacuation configuration.

81. The assembly of claim 75, wherein the tube includes an inner layer and an outer layer.

82. The assembly of claim 81, wherein the outer layer forms the sealing surfaces.

83. The assembly of claim 81, wherein the inner layer forms the evacuation lumen.

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84. The assembly of claim 81, wherein the inner layer comprises a first material and the outer layer comprises a second, different material.

85. The assembly of claim 84, wherein the second material is an expandable material.

86. The assembly of claim 75, wherein the evacuation lumen is shorter than the inflation lumen.

87. An evacuation sheath assembly comprising:
an elongated tube defining an expandable evacuation lumen having a compressed delivery configuration and an expanded operational configuration, and
a first sealing surface configured to form a seal within a catheter and a second sealing surface configured to form a seal with a blood vessel.

88. The evacuation sheath assembly of claim 87, wherein the evacuation lumen is expandable by inflation of the sealing surfaces.

89. The evacuation sheath assembly of claim 87, wherein the evacuation lumen is expandable by actuation of a wire connected to a distal end of the evacuation lumen.

90. The evacuation sheath assembly of claim 87, wherein the evacuation lumen is maintained in the compressed delivery configuration by a delivery sheath.

91. The evacuation sheath assembly of claim 87, wherein the second sealing surface is located on a distal portion of the evacuation sheath assembly and the first sealing surface is located on a proximal portion of the evacuation sheath assembly.

92. The evacuation sheath assembly of claim 87, wherein the second sealing surface includes an inflatable balloon.

93. The evacuation sheath assembly of claim 87, wherein the second sealing surface includes an outer surface of the evacuation lumen.

94. The evacuation sheath assembly of claim 91, wherein the first and second sealing surfaces are inflatable balloons.

95. The evacuation sheath assembly of claim 94, wherein the second sealing surface is expandable to a greater diameter than the first sealing surface.

96. The evacuation sheath assembly of claim 87, further comprising a radiopaque marker on a surface of the evacuation lumen.

97. A combination for isolating fluid communication between a blood vessel and a catheter, comprising:

a catheter having a lumen; and

an evacuation sheath assembly configured to move within the lumen of the catheter and having an evacuation lumen and first and second sealing surfaces.

98. The combination of claim 97, wherein the evacuation lumen is configured to isolate fluid communication between the blood vessel and the catheter lumen.

99. The combination of claim 97, wherein the first sealing surface includes a proximal portion of the evacuation sheath assembly configured to seal against the lumen of the catheter.

100. The combination of claim 97, wherein the second sealing surface is located on a distal portion of the evacuation sheath assembly.

101. The combination of claim 97, wherein the first and second sealing surfaces include expandable surfaces.

102. The combination of claim 97, wherein the first and second sealing surfaces include inflatable balloons.

103. The combination of claim 97, wherein the second sealing surface is configured to create a seal between the evacuation sheath assembly and the blood vessel.

104. The combination of claim 97, wherein the second sealing surface includes an inflatable balloon on a distal portion of the evacuation sheath assembly and the first sealing surface includes an inflatable balloon on a proximal portion of the evacuation sheath assembly.

105. The combination of claim 97, wherein the first sealing surface is located on a proximal portion of the evacuation sheath assembly and is configured to form a seal with the lumen of the catheter, and wherein the second sealing surface is located on a distal portion of the evacuation sheath assembly and is configured to form a seal between the evacuation sheath assembly and the blood vessel.

106. The combination of claim 97, wherein the evacuation sheath assembly further comprises an inflation lumen in fluid communication with the sealing surfaces.

107. The combination of claim 97, further comprising a marker on a proximal portion of the evacuation sheath assembly.

108. The combination of claim 97, further comprising a marker adjacent at least one of the first and second sealing surfaces.

109. The combination of claim 97, further comprising a soft flexible tip on a distal end of the evacuation sheath assembly.

110. The combination of claim 97, wherein a distal end of the evacuation lumen is formed at an angle.

111. The combination of claim 97, wherein proximal and distal ends of the evacuation lumen are formed at angles.

112. The combination of claim 97, further comprising a flexible, steerable tip on a distal end of the evacuation sheath assembly.

113. An evacuation sheath assembly comprising:
an elongated tube defining an evacuation lumen having proximal and distal ends;

a proximal sealing surface at a proximal end of the tube configured to form a seal with a catheter; and

a distal sealing surface configured to form a seal with a blood vessel.

114. The evacuation sheath assembly of claim 113, wherein the ends of the lumen are formed at angles.

115. The evacuation sheath assembly of claim 113, wherein the proximal sealing surface includes an inflatable balloon.

116. The evacuation sheath assembly of claim 113, wherein the distal sealing surface includes an inflatable balloon.

117. The evacuation sheath assembly of claim 113, wherein the proximal and distal sealing surfaces include inflatable balloons, and wherein the distal balloon is larger than the proximal balloon.

118. The evacuation sheath assembly of claim 113, wherein the evacuation lumen includes a proximal portion of a first diameter and a distal portion of a second diameter.

119. The evacuation sheath assembly of claim 118, wherein the first diameter is smaller than the second diameter.

120. The evacuation sheath assembly of claim 113, wherein the evacuation lumen is expandable from a delivery configuration to an operational configuration.

121. The evacuation sheath assembly of claim 120, wherein the evacuation lumen is compressible by a delivery sheath to maintain the lumen in the delivery configuration.

122. The evacuation sheath assembly of claim 120, wherein the evacuation lumen includes inner and outer layers.

123. The evacuation sheath assembly of claim 122, wherein the evacuation lumen is expanded from the delivery configuration to the operational configuration by expanding the outer layer.

124. The evacuation sheath assembly of claim 123, wherein the outer layer is inflatable.

125. The evacuation sheath assembly of claim 120, wherein the evacuation lumen is an expandable coated, braided sheath.

126. The evacuation sheath assembly of claim 125, wherein the braided sheath comprises a metal.

127. The evacuation sheath assembly of claim 125, wherein the braided sheath comprises a polymer.

128. The evacuation sheath assembly of claim 113, further comprising a pressure transducer in fluid communication with the evacuation lumen.

129. The evacuation sheath assembly of claim 120, wherein the proximal and distal sealing surfaces are inflatable balloons.

130. The evacuation sheath assembly of claim 129, wherein the distal balloon is larger than the proximal balloon.

131. The evacuation sheath assembly of claim 120, wherein the proximal and distal sealing surfaces include portions of an outer surface of the evacuation lumen.

132. The evacuation sheath assembly of claim 113, further comprising a proximal shaft portion attached to a proximal end of the elongate tube.

133. The evacuation sheath assembly of claim 132, wherein the evacuation lumen is expandable and wherein an actuation wire for expanding the evacuation lumen passes through the proximal shaft portion.

134. The evacuation sheath assembly of claim 132, further comprising at least one radiopaque marker on the proximal shaft portion.

135. The evacuation sheath assembly of claim 113, further comprising a flexible tip on a distal end of the assembly.

136. The evacuation sheath assembly of claim 113, wherein a distal end of the evacuation lumen is formed at an angle.

137. The evacuation sheath assembly of claim 113, further comprising at least one marker adjacent at least one of said proximal and distal sealing surfaces.

138. An evacuation sheath assembly comprising:

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an elongated tube defining an evacuation lumen having open proximal and distal ends and an inflation lumen having an open proximal end and a closed distal end; and

a first sealing region on a proximal portion of the evacuation lumen and a second sealing region on a distal portion of the evacuation lumen, wherein at least one of the first and second sealing regions is in fluid communication with the inflation lumen, and wherein the first sealing region is expandable to a first diameter and the second sealing region is expandable to a second diameter different than the first diameter.

139. An evacuation sheath assembly comprising:

an elongated tube defining an inflation lumen and an expandable evacuation lumen having a compressed configuration and an expanded configuration; and

a plurality of expandable surfaces along a length of the tube, wherein a most proximal expandable surface forms a proximal sealing surface and wherein a most distal expandable surface forms a distal sealing surface, and wherein expansion of the plurality of expandable surfaces expands the evacuation lumen from the compressed configuration to the expanded configuration.

140. An evacuation sheath assembly comprising:

an elongated sheath defining an evacuation lumen having open proximal and distal ends, wherein the sheath is expandable from a delivery configuration to an operational configuration;

a proximal hollow shaft connected to a proximal end of the sheath; and

an actuation wire connected to a distal end of the sheath, the actuation wire being movable within said shaft from a distal position to a proximal position to expand said sheath.

141. A method of treatment of a blood vessel, comprising:

- advancing a guide catheter proximate to the blood vessel;
- advancing an evacuation sheath assembly through the guide catheter and into the blood vessel while retaining a proximal portion of the evacuation sheath assembly within the guide catheter;
- creating a first seal between the proximal portion of the evacuation sheath assembly and the guide catheter;
- creating a second seal between a distal portion of the evacuation sheath assembly and the blood vessel;
- stopping normal antegrade blood flow within the blood vessel;
- treating a stenosis within the blood vessel;
- causing retrograde flow within the blood vessel to thereby remove embolic material dislodged during the treating and carried by the retrograde flow into the evacuation sheath assembly; and
- re-establishing normal antegrade blood flow within the blood vessel.

142. An evacuation sheath assembly, comprising:

- an elongated tube defining an expandable evacuation lumen having first a first delivery configuration and a second operational configuration; and
- a sealing surface on a distal portion of the evacuation lumen, the sealing surface having a non-sealing configuration that corresponds to the first delivery

configuration and a sealing configuration that corresponds to the second operational configuration, wherein the sealing configuration is configured to create a seal with a blood vessel.

143. An evacuation sheath assembly, comprising:

an elongated tube defining an evacuation lumen having open proximal and distal ends and an inflation lumen having an open proximal end and a closed distal end;

at least one inflatable sealing surface in fluid communication with the inflation lumen; and

a soft steerable tip on a distal end of the elongated tube.

144. An evacuation sheath assembly, comprising:

an elongated tube defining an evacuation lumen having open proximal and distal ends and an inflation lumen having an open proximal end and a closed distal end; and

at least one inflatable sealing surface in fluid communication with the inflation lumen;

wherein the open distal end of the evacuation lumen is angled.

145. An evacuation sheath assembly, comprising:

an elongated tube defining an evacuation lumen having open proximal and distal ends and an inflation lumen having an open proximal end and a closed distal end; and

first and second sealing surfaces on the tube;

wherein the open proximal end of the evacuation lumen is angled.

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146. An evacuation sheath assembly, comprising:

an elongated tube defining an evacuation lumen having open proximal and distal ends and an inflation lumen having an open proximal end and a closed distal end; and

at least one inflatable sealing surface in fluid communication with the inflation lumen;

wherein the evacuation lumen is shorter than the inflation lumen.

147. An evacuation sheath assembly, comprising:

an elongated tube defining an evacuation lumen having open proximal and distal ends and an inflation lumen having an open proximal end and a closed distal end; and

at least one inflatable sealing surface in fluid communication with the inflation lumen;

wherein a proximal portion of the evacuation lumen has a first diameter and a distal portion of the evacuation lumen has a second diameter larger than the first diameter.

148. A method for treating a diseased blood vessel, comprising:

positioning a guide catheter within the ostium of a target vessel;

advancing an evacuation sheath assembly through the guide catheter and beyond a major side branch of the target vessel;

forming a first seal between the target vessel and a distal portion of the evacuation sheath assembly;

forming a second seal between the catheter and a proximal portion of the evacuation sheath assembly; and

advancing an interventional device through a lumen of the evacuation sheath assembly to treat the target vessel.

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